



The American College of Chest Physicians (ACCP) and The CHEST Foundation

Comments to Anti-Infectives Drugs Advisory Committee of FDA

PART I: *Alvin Lever, MA, FCCP(Hon), Executive Vice President & CEO, ACCP,
Northbrook, IL*

Who We Are—The American College of Chest Physicians (ACCP), a Clinical Society, Founded in 1935 as the Clinical Society for Chest Specialists:

- A multidisciplinary not-for-profit society of more than 15,500 members worldwide.
- Membership includes: pulmonary and critical care physicians, cardiologists, thoracic and cardiac surgeons, allergists, anesthesiologists, pediatricians, nurses, and allied health professionals.
- ACCP Vision—The College is the leading resource for the improvement in cardiopulmonary health and critical care worldwide.
- ACCP Mission—To promote the prevention and treatment of diseases of the chest through leadership, education, research, and communication.

The CHEST Foundation—The Philanthropic Arm of the ACCP

- The CHEST Foundation was founded in 1996.
- Focus is education and disease prevention in the community and public health areas.
- Emphasis includes smoking cessation and prevention, asthma, and end-of-life issues in the critical care environment and awards for research and community service.
- Mission to provide resources to advance the prevention and treatment of diseases of the chest.

What We Do—Examples Include:

- Publish *CHEST*, with the largest worldwide circulation of any clinical respiratory journal.
- Conduct annual national and international scientific assemblies.
- Offer Continuing Medical Education (CME) to physicians and other health care professionals.
- Develop and distribute Clinical Practice Guidelines and Consensus Statements for major clinical concerns such as sepsis. An Example of the American College of Chest Physicians/Society of Critical Care Medicine (ACCP/SCCM) 1992 Consensus Conference on Definitions of Sepsis is available as a reprint from *CHEST* Vol. 101, p. 1644 – 1655, June 1992 issue.
- Collaborate with the World Health Organization and others on issues concerning the prevention and treatment of respiratory diseases, such as chronic obstructive lung diseases, and global controls on tobacco and smoking.

- Consult with government agencies on issues such as new medical treatments, prevention of tobacco-related disease, support for initiatives, critical care physician's workforce issues, Medicare reimbursement, and health care reform.

PART II: *Curtis N. Sessler, MD, FCCP, Professor of Medicine, Virginia Commonwealth University Health System, Medical Director of Critical Care, Medical College of Virginia Hospitals*

Incidence and Treatment of Sepsis

- Every year, severe sepsis strikes an estimated 750,000 people in the United States -- killing approximately 215,000 people annually. Its incidence is expected to rise to nearly one million annually by the end of the decade.
- Sepsis currently is the leading cause of death in the non-coronary ICU.
- Historically, we have had treatment for severe sepsis. This includes antibiotics for direct treatment, fluids (vasopressors) to treat components of the derangements caused by severe sepsis and supportive therapy such as mechanical ventilation dialysis and nutrition.
- This new class of drugs and novel approach to treatment offers a new opportunity to ameliorate the adverse effects of severe sepsis through altering its complex pathophysiology.
- In the course of my medical career, and that of many other physicians, I have witnessed hundreds of critically ill patients who have had infections and developed severe sepsis. Many such patients succumb to the condition of severe sepsis, despite aggressive management with conventional tools, including antibiotics, fluids, vasopressor, and supportive measures.
- It is important to emphasize that drotracogin alfa is a novel new class of agents which offers a new strategy for the treatment of sepsis (combination of anti-inflammatory, anti-coagulant, pro-fibrinolytic therapy) that appears to be effective at improving the chances of survival in the patient with severe sepsis.
- We salute the sepsis research that has been done to date and commend all involved for their efforts.
- We encourage you to take these points into consideration as you make your recommendation.